Advancing Payment Reform

Aligning MACRA payment model development with CMMI priorities

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Introduction

Congress has passed legislation and the Department of Health & Human Services (HHS), Centers for Medicare and Medicaid Services (CMS), has launched programs to drive incentives for adoption of Alternative Payment Models (APMs) for Medicare and other federal healthcare programs, to align healthcare provider and program interests to achieve better healthcare outcomes at a more sustainable cost. Medicare providers are being incentivized to embrace risk-based APMs; however, due to the limited number of these APMs operating across the country, only a small minority of Medicare clinicians have the attributes or opportunity to participate in these value-based care models. It is not clear whether this condition can or will change given the current trajectory of model development, which raises serious questions about whether the incentives and existing models are sufficiently aligned to achieve the policy outcomes intended by Congress and HHS.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), often referred to as "the permanent doc fix," was enacted on April 16, 2015 as a way to address physician payment and spur the move to value-based payment models. Among other things, MACRA revised the Balanced Budget Act of 1997 (BBA '97) and eliminated the Sustainable Growth Rate (SGR) payment system for physicians treating Medicare patients. MACRA replaced the BBA '97 physician payment system with the Quality Payment Program (QPP),[i] which fundamentally changed the way Medicare pays clinicians, with incentives and penalties to encourage value over volume billing. Specifically, the QPP streamlines multiple previously existing quality programs under the Merit Based Incentive Payment System (MIPS) and provides bonus payment for participation in eligible Advanced Alternative Payment Models (APMs).[ii] The QPP began its first performance year on January 1, 2017.

While Congress had every intention of legislating a "permanent" doc fix, substantial questions have been raised about the original design and long-term sustainability of the QPP. On January 11th, 2018, the Medicare Payment Advisory Commission (MedPAC) voted 14-2[iii] to recommend that Congress scrap the MIPS program and replace it with a new value program. In February, Congress made significant changes to the MIPS program as part of the Bipartisan Budget Act of 2018[iv] and CMS announced plans to roll out a "complete overhaul" of the MIPS Advancing Care Information performance category.[v] MedPAC has also expressed reservations about the bonus payment scheme for participation in Advanced APMs under the QPP[vi] and most recently, the Trump Administration proposed adjustments to the bonus payment system for Advanced APMs under the QPP that were very similar to the MedPAC proposal.[vii]

Despite the Congressional changes and MedPAC recommendations for the QPP, general directional support for the movement from volume to value in Medicare still appears to be strong.[viii] Members of Congress from relevant committees of jurisdiction, as well as the Administration[ix] appear to be committed to the creation and adoption of additional APMs, while also taking a critical look at existing APMs.[x] Indeed, HHS Secretary Alex Azar recently told stakeholders that "there is no turning back to an unsustainable system that pays for procedures rather than value."[xi] Provider group support seems to be strong as well.[xii]

Yet, despite the support for APMs to be a primary vehicle to move from volume to value, stakeholders have expressed concerns that there are not enough APM options available for clinicians in the QPP. In fact, CMS estimates that only 185,000 to 250,000 of clinicians – or less than 20% of all eligible clinicians – will meet the definition of a QP next year[xiii]. This lag in APM development and adoption has the potential to slow the migration from fee-for-service to value-based care in the QPP and across the health care system.

This paper explores the evolution of APMs since the passage of MACRA, examines barriers to new APM development and adoption, and raises questions about the limits of future APM proliferation.

Current Medicare APM options

While development and testing of APMs by the Centers for Medicare and Medicaid Services (CMS) did not begin with the establishment of the QPP, MACRA was intended to accelerate widespread adoption of Advanced APMs,[xiv] including through establishment of the Physician-Focused Payment Model Technical Advisory Committee (PTAC), which was intended to facilitate the review of potential future APMs for adoption by clinicians.[xv] MACRA established standards for a payment model to be considered an Advanced APM, with providers participating in those Advanced APMs "eligible" to receive additional incentive payments under the QPP.

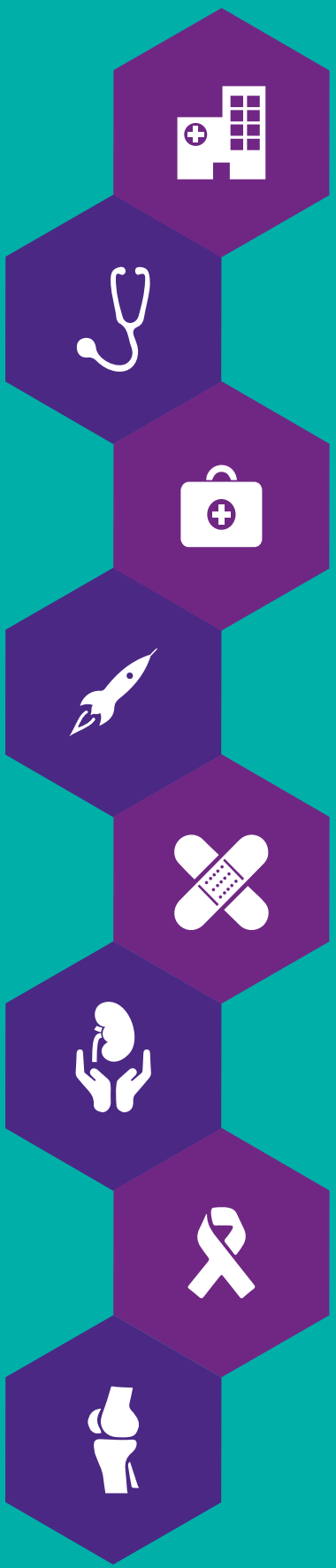
The QPP requires that qualifying models must (1) require participants to use certified electronic health record technology (CEHRT); (2) base payment on quality measures comparable to those used in the quality performance category of MIPS; and (3) require participating entities to bear "more than a nominal amount" of financial risk for monetary losses, or be a medical home model expanded under CMS authority. CMS has established technical requirements for meeting these statutory definitions in rulemaking.[xvi]

While the PTAC was established to recommend APMs for adoption by Medicare, CMS is the only entity authorized and funded to approve testing or expansion of new APM models for Medicare,[xvii] including those designed to meet the definition of an Advanced APM in the QPP; CMS is also authorized to approve Other Payer Advanced APMs that clinicians can participate in to meet the All-Payer threshold in future years of the program. Although clinicians will be able to use Other Payer APMs to meet the increasing revenue and patient QP threshold in future years, they must still have at least 25% of their revenue in qualifying Medicare Advanced APMs to be eligible for the APM bonus. Thus, continued participation in a minimum number of Medicare APMs will continue to be a prerequisite to meeting All Payer requirements.

With the exception of the Medicare Shared Savings Program (MSSP), which was created by statute, all of the current Medicare APMs have been developed through the Center for Medicare and Medicaid Innovation (CMMI) under §1115 waiver authority to test potential models for their impact on Medicare cost and quality. According to the Affordable Care Act (ACA), if the CMS Office of the Actuary certifies that the model saves money while not reducing quality, the HHS Secretary has the authority to continue the model test period or expand the model for broader implementation. [xviii]

The MSSP established by the ACA, began in April 2011 and currently accounts for the largest proportion of APM participation in Medicare (serving more than 10 million beneficiaries in all states, DC, and Puerto Rico).[xix] Providers participating in MSSP Accountable Care Organizations (ACOs) assuming downside financial risk (18% of current participants) are considered eligible for QP status if they meet the required revenue (25%) and patient threshold (20%). In addition, CMMI has created and launched other Advanced APM options for Medicare providers: Next Generation ACO Model, Comprehensive Primary Care Plus, Comprehensive ESRD Care Model (downside risk option); Oncology Care Model (downside risk option); Comprehensive Care for Joint Replacement (Track 1 with certified EHR technology); and the Vermont All-Payer ACO Model. These models represent all of the options for clinicians to meet the QP standard in the 2018 QPP Performance Year.

Figure 1. Advanced alternative payment models, QPP 2018 performance year



Medicare Shared Savings Track 2
(currently 8 ACOs, 1% of total)

Medicare Shared Savings Track 3
(currently 38 ACOs, 7% of total)

Medicare Shared Savings Program Track 1+Model
(currently 55 ACOs; 10% of total)

Next Generation ACO Model
(Currently 51)

Comprehensive Primary Care Plus
(2,965 primary care practices)

Comprehensive ESRD Care Model
(currently 37 total ESCOs)

Oncology Care Model, 2-+sided risk
arrangement (currently 187 total practices)

Comprehensive Care for Joint Replacement (CJR)
Payment Model (Track 1 – CEHRT)

*Vermont Medicare ACO Initiative (part of the Vermont All-payer ACO Model) will also qualify as an Advanced APM

Despite CMMI efforts to increase Advanced APM options, including launch of the MSSP Track 1+ option this year, a December 2017 final rule cancelled certain episode payment models,[xx] which will reduce the number of providers meeting QP status in 2018. Specifically, the rule cancelled three models expected to be Advanced APMs in 2018 (Coronary Artery Bypass Graft (CABG) Model, Acute Myocardial Infarction (AMI) Model, and Surgical Hip/Femur Fracture Treatment (SHFFT) Model). The Rule also makes participation in the Comprehensive Care for Joint Replacement (CJR) model voluntary for hospitals in 34 of the 67 Metropolitan Statistical Areas (MSAs) currently required to participate and for low-volume and rural hospitals in all MSAs.

Although many hospitals and other stakeholders who opposed mandatory participation in the models welcomed this announcement, cancellation will reduce the number of additional providers likely to be QPs in 2018. The cancellation of the Rule also pulled back a formal policy establishing an order of precedence for addressing model overlap – the situation in which beneficiaries are treated by providers in multiple models.

In order to fill some of the gap from the cancelled mandatory models, CMMI announced that the voluntary Bundled Payments for Care Improvement Advanced (BPCI Advanced) model would launch in October 2018. Under this model, which will qualify as an Advanced APM, participants must take on financial risk (with required quality benchmarks) for the total cost of care associated with one of 32 clinical episodes.[xxi] While many providers welcomed the new option, post-acute care providers were discouraged that the model—currently limited to only acute care hospitals and physician groups— would not allow them to be participants,[xxii] potentially leaving a gap that some anticipated the model could have filled.

Although CMMI has made efforts to increase the number of Medicare payment models available to providers as Advanced APMs, many providers in certain geographies, specialties, and practice settings still lack viable options for APM participation.[xxiii] CMMI to date has not been able to produce enough viable, scalable models to meet the interest and potential demand created by MACRA. And in fact, the need to conduct and evaluate model results in the scientifically valid and analytically rigorous way intended under the law is incompatible with large-scale or rapidly proliferating and confounding models. In other words, there may be natural limits to the number of models that CMS can manage in any geographic area, and still be able to draw valid conclusions about any of them. Concerns about model overlap may lead to resistance on the part of existing model participants and reluctance on the part of HHS and CMMI to initiate new models at the expense of existing demonstrations that are still evolving. Given this reality, at a minimum, another mechanism for APM development that allows for provider community input and ideas is needed. Congress envisioned that the PTAC could fulfill this role, but to date, HHS has not adopted a single model recommended by the PTAC for testing.

The intended role of the Physician-focused Payment Model Technical Advisory Committee (PTAC)

Congress established PTAC[xxiv] to "provide comments and recommendations to the Secretary [of Health and Human Services]…on physician-focused payment models" submitted by individuals and stakeholder entities. Yet, more than a year after PTAC received its first formal proposal and after having recommended six models (out of fourteen full proposals reviewed) for limited-scaling testing or full launch, HHS has not responded to any recommendation made since April of 2017.

A Preliminary Review Team (PRT) of PTAC has examined eighteen model proposals, and the full committee has issued final recommendations on eleven models—one other was recommended for revision and resubmission. The PTAC most recently voted on seven proposals[xxv] at their public meeting on December 18–19, 2017; the PTAC released its formal recommendations to the HHS Secretary on these models on March 23rd. PTAC will consider seven more models on March 26th and 27th and June 14th and 15th. (See Table 1 for summary of models reviewed, recommended, and HHS decision). Letters of intent have been submitted for at least 16 other model proposals.

Figure 2. Status of Physician-Focused Payment Models (PFPMs) at least under consideration by Preliminary Review Team (PRT), as of March 20, 2018

PRT Report Status	Final PTAC Recommendation	Secretary Decision
Home Hospitalization: An Alternative Payment Model for Delivering Acute Care in the Home Meets 9 or 10 criteria; full committee consideration in March	**Hospital at Home Plus** Recommended for testing	**ACS-Brandeis Advanced APM** Submitter to address design concerns before HHS makes final decision about limited-scale testing
Intensive Care Management in Skilled Nursing Facility Alternative Payment Model Unanimously meets all 10 criteria; full committee consideration in March	**Oncology Bundled Program Using CNA-Guided Care** Recommended for limited-scale testing	**Project Sonar** Declined to pursue; but involve submitters in future specialty-based models
Patient and Caregiver Support for Serious Illness Meets 8 of 10 criteria; full committee consideration in March	**Advanced Care Model (ACM) Service Delivery and Advanced Alternative Payment Model** Recommended submitter revise and resubmit; Second PRT determined resubmission unanimously meets all criteria; Full committee deliberation of resubmission in March 2018	**COPD and Asthma Monitoring** No implementation or further action
Acute Unscheduled Care Model (AUCM): Enhancing Appropriate Admissions PRT report forthcoming; full committee consideration in June	**Advanced Primary Care: A Foundational Alternative Payment Model (APC-APM)** Recommended for limited-scale testing	
CMS Support of Wound Care in Private Outpatient Therapy Clinics PRT report forthcoming; full committee consideration in June	**Incident ESRD Clinical Episode Payment Model** Recommended for testing	
The Patient-Centered Headache Care Payment (PCHCP) PRT report forthcoming; full committee consideration in June	**Multi-provider, Bundled Episode-of-Care Payment Model for Treatment of Chronic Hepatitis C Virus (HCV)** Not recommended for testing	
	LUGPA APM for Initial Therapy of Newly Diagnosed Patients with Organ-Confined Prostate Cancer Not recommended for testing	
	Annual Wellness Visit Billing at Rural Health Clinics Does Not Meet Criteria of Alternative Payment Model	
	Medicare 3 Year Value Based Payment Plan (Medicare 3VBPP) Not Considered a Physician Payment Model	

While the PTAC is an important vehicle for harnessing stakeholder input for the creation of additional APMs for providers across the country, early experience suggests there are areas for improvement and ways to ease the process for submitters and reviewers alike. Suggestions for improvements in the process were highlighted in a letter from the PTAC to then-HHS Secretary Tom Price in late Summer 2017;[xxvi] they were also discussed during a House Energy and Commerce Committee hearing on November 8, 2017[xxvii] and showcased in a panel presentation at the Eighth National Alternative Payment Model (APM) and Accountable Care Organization (ACO) Summit on June 28 and 29, 2017.[xxviii] Most recently, the Bipartisan Budget Act, signed into law in February 2018, included a provision to attempt to address some of these process shortcomings discussed below.[xxix]

What is PTAC looking for in an APM?

Although MACRA established broad parameters for how PTAC should assess physician-focused payment model submissions, considerable discretion was given to the committee to decide how to weight the various criteria. In its Request for Proposals (RFP),the committee designated three criteria as high priority:[xxx]

1. broadening the current CMS APM portfolio by addressing a payment issue in a new way or providing APM opportunities to physicians with limited current APM options
2. improving health care quality at no additional cost, maintaining quality while decreasing costs, or both improving quality and decreasing costs
3. addressing in detail how the proposed payment methodology differs from current methodologies and achieves the goals of the other criteria.

While PTAC chose to place emphasis on these criteria, HHS has provided no formal guidance on how it will prioritize the various criteria or whether it shares this priority list or selection emphasis in making a final determination about whether to test the physician-focused payment model (PFPM).

PTAC Members Paul Casale, M.D. and Len Nichols, Ph.D.,[xxxi] stressed at the APM and ACO Summit that the PTAC is looking for "bottom up"[xxxii] approaches for payment innovation. Such approaches can help address current gaps in payment arrangement availability for underrepresented specialties, as well as existing deficiencies in care for certain clinical conditions. In order to be successful, Drs. Casale and Nichols explained that APM developers must clearly articulate both the current clinical or delivery problem, and how the payment arrangement is likely to address the payment gap or deficiency in care.

A successful submission should be able to draw a clear link between the payment model and opportunities for quality improvement and better patient care within a brief model description.[xxxiii] In this respect, Casale emphasized that submitters so far have been "passionate" about changing care delivery, leading him to be "encouraged" by possible future model submissions.[xxxiv] However, Casale and Nichols also suggested that future submitters should explore ways to build new partnerships and collaborations to address unique challenges that cut across specialties and practice settings, and better connect payment and clinical innovation.

Current provider considerations for developing new APMs

According to stakeholders, when creating a new APM and submitting a proposal to PTAC, a model developer must carefully consider how the payment arrangement reinforces or complements care delivery reforms. Some alternative payment models are developed based on existing delivery transformation efforts, by building the incentives and payment around the delivery system changes. For example, when submitting its proposal for an advanced care model to PTAC, the Coalition to Transform Advanced Care (C-TAC) sought to first change the way that patients with advanced illness and chronic conditions are cared for, including through improving post-acute care services. They then created a per-member per-month payment along with potential retrospective shared savings to incentive these kinds of care transformation.[xxxv]

On the other hand, other submitters have chosen to develop a payment model that can then be adapted to a variety of practice settings, conditions, and delivery transformation efforts. This was the approach taken by the American College of Surgeons (ACS) with its bundled-payment-driven model. According to Dr. Frank Opelka, Medical Director of Quality and Health Policy for the Division of Advocacy and Health Policy at the ACS, the ACS partnered with Brandeis University to develop 54 payment episodes of care that can be implemented across care settings without prescribing the care approaches required to be implemented.[xxxvi]

Regardless of the payment approach taken, model submitters and PTAC members agree that incentives must be aligned across all providers and settings, and that provider groups must not neglect payment or delivery transformation. In other words, performance and behaviors must be directly connected to reimbursement and must reward providers across the care continuum and at all levels from physicians down to non-clinical care coordinators. The payment model must also provide incentives for healthcare transformation approaches that meet patient needs, and where possible, engage patients and family members in the self-management of their care.

Payment model developers must also consider whether the arrangement relies on prospective payment through a capitated arrangement or retrospective financial reconciliation. This will be driven at least in part by the type of payment model—i.e. more likely prospective payments for capitated arrangements, and retrospective reconciliation for bundles or shared savings models—but the incentives for change can be significantly impacted by the approach taken. For example, providing prospective payment provides a predictable funding stream and financial incentives to drive more active management of costs throughout the course of the payment period. These broad considerations for providers seeking to propose or develop an APM are likely to be relevant regardless of the practice setting, provider type, or existing payment arrangements.

What is CMS looking for in an APM?

After a model is recommended for consideration by the PTAC, it must still get the approval of the HHS Secretary before it can be considered for testing. In making such a determination, the Secretary and CMS must carefully consider factors such as how such a model fits within their current portfolio, how the model may impact federal spending, and whether it can potentially be scaled. As noted above, HHS has formally commented on three PFPMs assessed by PTAC, and not fully embraced any of those models—concluding that one model should not be implemented,[xxxvii] that CMS work closely with another submitter to address model design concerns before making a final determination,[xxxviii] and that CMS involve another submitter in future specialty models.[xxxix]

In the three letters commenting on PTAC approved proposals, HHS lays out the main concerns with the proposed models, including uncertainty about the payment methodology, quality measurement, care coordination impacts, and applicability to the Medicare fee-for-service population. Although some of these considerations align with those guiding assessment of PFPMs by PTAC, the weighting of considerations is likely different for CMS. Indeed, in an APM Design Toolkit available on the QPP website,[xl] CMS lays out 20 different design factors that it uses to consider new models.

In addition to considerations about clinical and financial impact, evidence base, and stakeholder interest, CMS must consider how the model will affect the agency and other federal healthcare programs. For example, it must examine how a new model aligns with HHS goals, others payers and CMS programs, and current or anticipated models; the size of CMS investment required; operational feasibility for CMS; waiver authority; scalability within federal healthcare programs; and feasibility for evaluation of impacts. These additional considerations are not explicitly required of model submitters to PTAC, but are clearly driven by a desire to ensure that a model is in the best interest of the federal government—thus creating a potential disconnect between what PTAC and CMS respectively view as good models for testing and implementation. To date, there has been little transparency on how the submitted proposals have stacked up against these CMS priorities.

Even if HHS were to agree that a model is ready for testing, it must still determine the scope of the model launch (e.g., limited-scale testing, implementation, implementation as a high priority).[xli] CMMI is likely to use a similar approach to other models it has launched—a request for proposals is released to identify providers or regions that are equipped to test the model and help identify potential needed changes before moving to a larger scale deployment. Importantly, the model test must be constructed in such a way as to allow for a valid comparison group that is unaffected by the model's interventions— a process that is ever more challenging as models proliferate. After launch, CMS will then need to conduct periodic formal evaluations to determine whether the model is on track to meet its goals and whether it is ultimately successful and worthy of formal expansion.[xlii] The CMS Actuary has thus far certified only two CMMI models (Pioneer ACO Model and Medicare Diabetes Prevention Program) for expansion and further testing.[xliii]

Current challenges and barriers to more rapid implementation

The process for getting a PFPM off the drawing board is clearly not an easy one, given the levels of scrutiny and procedural barriers to be cleared before it can even be tested. In addition to the burden presently being on the submitter to develop a successful payment model, there remain some significant barriers to more effective consideration of those models by PTAC. These barriers include the current process requirements and the amount of time needed to fully review submissions.

Inefficient review process by (FACA) design

There are currently 11 committee members on PTAC, supported by a small staff through the Office of the Assistant Secretary for Planning and Evaluation (ASPE). Initial committee members were appointed in 2015, which gave the committee about a year to get things in place prior to the Fall 2016 release of regulations for the first performance year of the QPP (2017). During that first year of operation, the committee released a request for proposals and started building the necessary infrastructure for its operations. When proposals are submitted to PTAC they are sent to a Preliminary Review Team (PRT) comprised of a selected subset of committee members to review the proposal in detail. During this time additional details are asked of submitters and the PRT will draft an initial report for full committee review. The full committee will then discuss and deliberate about the model and make a final recommendation to the HHS Secretary about whether it believes the model should be tested or implemented.

Although the use of a PRT reduces the burden of the entire committee having to do a thorough examination of every proposal, the full committee is subject to the Federal Advisory Committee Act (FACA)[xliv] and is therefore required to meet (and deliberate) in public, and committee members are prohibited from discussing their work outside of these public settings. The prohibition on discussions outside of public meetings limits the extent of the discussion and fact finding the committees members can engage in, resulting in committee member views that may change significantly over the course of deliberation. For example, there have been some cases in which the decision on a given model has changed between the PRT report and the full committee discussion, once additional considerations are raised by those not on the PRT.[xlv]

On the other hand, early evidence suggests the PRTs may actually be better able to provide a thorough and reliable assessment of a model's potential for acceptance. None of the PRTs recommended any of the first three models reviewed for implementation or testing. It was only after review and discussion by the full committee that two of those models were recommended for "limited testing," a designation created by the PTAC to allow "meritorious" models to move forward that may need further technical assistance before wider deployment.[xlvi] Although there are few test cases so far, early examples suggest that the larger committee may reach a more accommodating decision than that of the PRT. [See appendix case study].

PTAC members have emphasized that the PTAC may quickly reach its capacity for reviewing models in a timely fashion. Although the amount of time deliberating as a full committee is relatively limited, the individual members spend a considerable amount of time as part of the PRTs reviewing the proposals and supporting materials, communicating with submitters on follow-up questions, and producing their initial PRT report with recommendations to the full PTAC. A significant amount of this work must be done by individual committee members outside of their quarterly scheduled meetings and cannot be delegated to ASPE or other staff. Furthermore, although members have significant qualifying health

policy experience, they are volunteering their time without compensation for the significant amount of time they are contributing to the process. Given the significance of the time commitment required by members, Nichols estimates that the committee likely cannot review (from PRT to full committee vote) any more than six to eight models per quarter, potentially making it impossible for the PTAC to keep pace with the influx of newly proposed models. Additionally, there is no statutory language or guidance from HHS on how long the review process should take (from proposal submission to final HHS determination), leaving potential inconsistencies in review time across models and uncertainty for submitters.

Lack of technical assistance and support for submitters

While PTAC continues to receive Letters of Intent and formal proposal submissions for PFPMs, Jeffrey Bailet and Elizabeth Mitchell, PTAC Chair and Vice-Chair, respectively, emphasized to Congress in November of 2017 that there is a "material need for technical assistance for providers to develop and implement physician focused payment models (PFPMs) and APMs."[xlvii] PTAC is not allowed to provide any technical assistance to submitters. As structured, the PTAC can only make a recommendation as to whether a specific model should be considered for adoption and provide details on why, but cannot assist with addressing the deficiencies. Bailet and Mitchell were particularly concerned that small and rural practices lack the ability to afford technical assistance to redesign care and payment, let alone the infrastructure to effectively assume financial risk and participate in APMs. Additional HHS resources to provide access to analytics, technical, and quality improvement support could create a more diverse selection of PFPMs for consideration and potential implementation.

In addition, the PTAC members remain concerned that submitters lack access to appropriate data to support their proposals and undertake the approaches they set forth. Casale and Nichols noted that some models they've seen are conceptually sound and appear to adequately fill an existing gap, but simply lack the appropriate analytic rigor and rationale to be recommended for implementation. Providing submitters with templates of what a good model submission looks like, or access to data and analytics to improve model elements, such as risk adjustment methodology, could improve the likelihood of adoption. Bailet and Mitchell called for "community wide all-payer claims and clinical data sharing across communities" to successfully support and implement models. Allowing committee members to share their expertise with submitters, or at least creating a more iterative process between submitters and reviewers, could help to expedite the approval and launch of good ideas that currently lack the rigorous technical specification to be practical in the real world.

To address some of these concerns, a provision was passed as part of the Bipartisan Budget Act of 2018 that would allow PTAC to "provide individuals and stakeholder entities…initial feedback on such models…and prepare comments and recommendations regarding whether such models meet the criteria [established by MACRA]."[xlviii] Although this provision may allow PTAC members to provide more timely responses to submitters and allow for a faster revision and resubmission process, the scope of this flexibility is unclear. Specifically, it is ambiguous whether this initial feedback and recommendations may include those related to technical aspects of the proposed models, such as risk adjustment methodology, or if they must simply focus on whether the model "checks the box" for each of the established criteria.

Furthermore, although PTAC members may have an interest and willingness to share their expertise through initial comments and recommendations, this additional added process step may increase their time burden and already heavy workload, which could further slowdown their ability to review and deliberate on other model proposals. The voluntary nature of PTAC membership and the need for substantial technical assistance to meet HHS standards calls into question whether the legislative design of the PTAC is sufficient to realize its purpose of contributing to the availability of actual APMs.

Need for implementation flexibility and clarity on how models fit into larger APM development

In recognition of some of the uncertainties around the viability of certain PFPMs, PTAC has placed special emphasis on recommending certain models for "limited-scale testing." The committee believes that field testing will be critical for understanding unintended consequences and barriers to certain models before they are launched on a larger national scale, and encourages HHS to consider this approach for some of the models they have already reviewed. Other industry stakeholders have likewise encouraged CMMI to use limited-scale testing to accelerate innovation.[xlix] One possible approach would be a vehicle similar to CMMI's early Health Care Innovation Award (HCIA) awardees, where individual entities tested a concept. One successful example of this sort of limited-scale test was the Diabetes Prevention Program piloted by the Young Men's Christian Association (YMCA) of the USA (Y–USA),[l] which has since been expanded nationally into the Medicare Diabetes Prevention Program.[li]

Another overarching consideration for PTAC is the uncertainty of how PFPMs are expected to fit into the larger landscape of APMs being developed by CMS. Although CMMI is likely to continue developing models, the scope of testing of new payment arrangements and how quickly they may be approved and launched is unknown. Indeed, it is not clear how many models will be needed to meet the needs of physicians across the country who want to adopt APMs, or whether those that do launch will in fact be methodologically sound and likely to succeed. A June 2017 KPMG-AMA survey of 1,000 physicians on QPP knowledge and readiness found that more than one-half of physicians want more APM options, suggesting physicians think more work is needed to provide viable options.[lii] On the other hand, there is some evidence that providers doubt the ability of APMs, such as ACOs and bundled payment models, to effectively control healthcare costs,[liii] while others are experiencing "model fatigue" in which they struggle to decide which model makes the most sense for them.[liv] On top of this, as mentioned above, it is not clear that the current constraints around developing statistically sound and reliable model tests are even remotely compatible with supporting the number, specialization and geographic location of clinician demand for Advanced APMs.

A recent CMMI request for information (RFI)[lv] suggests that CMS is committed to developing additional APMs that meet clinician and patient needs, but the path to more rapid development and adoption of new PFPMs remains uncharted. Even setting aside design constraints, it takes a significant amount of time for a CMMI model to move from concept to implementation. The Center for Healthcare Quality & Payment Reform estimates that it takes CMMI more than 2 years to make an APM model concept available as a demonstration to selected participants, which must then be followed by several years of testing and refinement before it becomes available to all providers. In total, under current procedures, it could take 6 to 8, or more, years for CMMI to move an APM from concept to full implementation.[lvi] Without significant additional resources and investment it seems unlikely that this current process can support the launch of a sufficient number of models to meet the demand created by the QPP incentives. Given the significant time and resources required to launch a model, CMMI must work closely with the provider community to ensure that the Innovation Center launches not just more models, but the best models to meet current demands and gaps. Failing to launch models that appeal to providers could result in suboptimal participation and inadequate testing of approaches, and less efficient use of CMMI investments.

Additionally, it is unclear how new PFPMs may interact with existing APMs (both those through CMS and private payers), particularly with respect to financial reconciliation if a beneficiary, provider, or group is attributed to multiple models. This issue of model "overlap" has been and remains a challenge for CMS for both fairness of reimbursement terms and validity of model evaluation, respectively. It is not clear that CMS has a comprehensive strategy for ensuring that physicians are able to participate in the most appropriate model or models for them and be assessed fairly within each of those models. Some stakeholders have already expressed concerns about potential complex and counterproductive interactions between the BPCI Advanced model and ACO models in reconciling payment adjustments and rewards.[lvii] Additional guidance from CMS on expected interactions and if, and how, certain models take precedence (i.e., what payments and services are considered in financial reconciliation for each model and how potential shared savings or losses are reconciled) may assist PTAC when making decisions about which models to recommend to HHS. However, significant questions remain about the limits for numbers of models and degree of overlap that can be realistically managed under the current CMMI approach.

Next steps

The Physician-Focused Payment Model Technical Advisory Committee has helped accelerate new ideas for payment model innovation envisioned by MACRA. Submitters have commended the committee for its commitment to thoughtful review and meaningful feedback on proposals submitted to-date. Members of the Committee have similarly commended submitters for their passion and creative thinking about new ways to reimburse providers in ways that reward high-value care. Yet, more than a year after receiving its first proposal, not a single model has been approved for implementation or even limited testing by HHS. Changes in HHS leadership could either accelerate or further delay and complicate the consideration of models for testing. Regardless, several members of the Energy and Commerce Committee have already suggested a follow-up hearing with HHS officials to better understand its review process and plans for beginning to launch or test certain potentially viable models, so the pressure for process reforms will likely continue.[lviii]

Failure of HHS to adopt any of the PTAC recommendations begs a number of questions about the compatibility and alignment of PTAC and CMS policies and processes, such as:

1. Are organizational incentives adequately aligned to encourage CMMI advocacy and co-development of promising PTAC proposals?
2. Does HHS/CMMI have the appropriate organization and resources to adequately evaluate and work with promising PTAC proposals?
3. Does CMMI have an appropriate policy approach to integrating additional specialty-specific models into the fabric of the ongoing set of models without worsening already challenging reimbursement and evaluation complexities?
4. Are CMMI models with sufficient scale for Medicare population-level statistical validity the best or only way to test PTAC-generated innovations?
5. Is the idea of hanging the success of delivery system reform on sufficient APMs for all providers who would be willing to participate a realistic concept?
6. If not, is there an alternative approach to incentivize wider scale reforms?
7. Should there be more transparency on how proposals and models chosen align with CMS priorities?

Ensuring the continued sustainability and effectiveness of the PTAC will require addressing some of these growing challenges and questions, ensuring that the vision of the PTAC remains aligned with broader CMS and federal government objectives on payment reform innovation, and continuing to work with providers and payers alike to identify new ways to reward clinicians for providing high-value, low-cost care.

The continued evolution of the health care value agenda will depend on resolving barriers to much wider adoption of alternative payment arrangements that appropriately fill current gaps and are aligned with the goals of delivery system reform. PTAC's contribution to this process should either be leveraged to maximize the value they can contribute to this transformation of the healthcare system, or the PTAC itself should be reevaluated to assure that the public service being contributed by the PTAC members is not reduced to a meaningless exercise to satisfy a statutory requirement of MACRA.

Footnotes

[i] Centers for Medicare and Medicaid Services. What's MACRA? Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html

[ii] The QPP, encourages Medicare physicians to participate in Advanced APMs. These Medicare approved APMs reward providers for delivering high-quality, low-cost care to Medicare beneficiaries, but may also impose financial penalties for providers who do not satisfy the APM cost and quality performance standards. Additionally, and regardless of the financial success of the APM, the QPP provides generous financial incentives (5% bonus payment on all Medicare Part B reimbursement) for all who providers who meet the definition of a Qualifying Participant in an Advanced APM (QP) based on meeting a threshold of revenue or patients through an Advanced APM.

[iii] Dickson, Virgil. MedPAC votes 14-2 to junk MIPS, providers angered. *Modern Healthcare*. January 11, 2018. Available at http://www.modernhealthcare.com/article/20180111/NEWS/180119963

[iv] The Bipartisan Budget Act of 2018 (a) provides reduces the physician fee schedule update in 2019 from 0.50% to 0.25% percent, (b) removes the cost of in-office (Part B) drugs from the calculation of penalties and bonuses under MIPS, and (c) provides CMS with the authority to keep the MIPS Cost Category score weight at 10% through 2021, and prevents the category from ever increasing to more than 30% of the total MIPS score.

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[xi] Azar, Alex. Remarks on Value-Based Transformation to the Federation of American Hospitals. March 5, 2018. Available at https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-value-based-transformation-to-the-federation-of-american-hospitals.html?new

[xii] American Medical Association. Efforts to Improve Medicare Payment Reform. Available at https://www.ama-assn.org/practice-management/efforts-improve-medicare-payment-reform; American Academy of Family Physicians. AAFP Principles to Support Patient-Centered Alternative Payment Models. Available at https://www.aafp.org/dam/AAFP/documents/advocacy/payment/apms/ES-PatientCenteredAPM-121310.pdf; CAPG. Letter to Seema Verma, August 8, 2017. Available at http://www.capg.org/modules/showdocument.aspx?documentid=3965

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[xiv] Centers for Medicare and Medicaid Services. Strategic Objectives for the Quality Payment Program. Available at https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/Quality-Payment-Program-Key-Objectives.pdf

[xv] Patrick Conway Hearing on MACRA before House Energy and Commerce Health Subcommittee. Additional Questions for the Record. March 17, 2016. Available at http://docs.house.gov/meetings/IF/IF14/20160317/104683/HHRG-114-IF14-Wstate-ConwayP-20160317-SD002.pdf

[xvi] Centers for Medicare and Medicaid Services. CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year. Federal Register 82(220): 53568-54229. Available at https://www.federalregister.gov/documents/2017/11/16/2017-24067/medicare-program-cy-2018-updates-to-the-quality-payment-program-and-quality-payment-program-extreme

[xvii] Section 1115A. Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2010).

[xviii] Sec 1115A of the Affordable Care Act stipulates that in order to expand a CMMI model, (1) the Secretary must determines that such expansion is expected to (A) reduce spending under applicable title without reducing the quality of care; or (B) improve the quality of patient care without increasing spending; (2) the Chief Actuary of the Centers for Medicare & Medicaid Services must certify that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and (3) the Secretary must determine that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals.

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[xxv] PTAC Meeting Agenda. December 18-19, 2017. Available at https://aspe.hhs.gov/system/files/pdf/255736/December17PublicMeetingAgenda.pdf

[xxvi] Bailet, Jeffrey. Letter to The Honorable Thomas Price. August 4, 2017. Available at https://aspe.hhs.gov/system/files/pdf/255906/PTACLetterSecPriceLessonsLearned.pdf

[xxvii] House Energy and Commerce Committee. MACRA and Alternative Payment Models: Developing Options for Value-based Care. November 8, 2017. Available at https://energycommerce.house.gov/hearings/macra-alternative-payment-models-developing-options-value-based-care/

[xxviii] Eighth National Alternative Payment Model (APM) and Accountable Care Organization (ACO) Summit. June 28-29, 2017. Arlington, Virginia. https://acosummit.com/

[xxix] Bipartisan Budget Act of 2019. Pub.L. 115–123. Signed by President, February 9, 2018.

[xxx] Request for Proposals: Medicare Physician-Focused Payment Models. February 21, 2017. https://aspe.hhs.gov/system/files/pdf/226776/RFP.pdf

[xxxi] Paul Casale, Executive Director of New York Quality Care; Len Nichols, Director, Center for Health Policy Research and Ethics, George Mason University. Future Directions for APM Development: The Role of P-TAC. Eighth National Alternative Payment Model (APM) and Accountable Care Organization (ACO) Summit. June 29, 2017. Washington, DC.

[xxxii] Casale, Paul. Future Directions for APM Development: The Role of P-TAC. Eighth National Alternative Payment Model (APM) and Accountable Care Organization (ACO) Summit. June 29, 2017. Washington, DC.

[xxxiii] Although submitters are allowed to provide appendices to support their proposals, the PTAC chose to limit the official proposal submission to 20 pages in order to encourage submitters to develop a clear and succinct explanation of what sets their model apart from existing payment arrangements. Despite the page limits, PTAC members and staff have conducted extensive follow-up with submitters to address outstanding questions and concerns.

[xxxiv] Casale, Paul. Future Directions for APM Development: The Role of P-TAC. Eighth National Alternative Payment Model (APM) and Accountable Care Organization (ACO) Summit. June 29, 2017. Washington, DC.

[xxxv] Khue Nguyen, PharmD. Chief Operating Officer, C-TAC Innovations. New APMs in Development for QPP. Eighth National Alternative Payment Model (APM) and Accountable Care Organization (ACO) Summit. June 28, 2017. Washington, DC.

[xxxvi] Frank G. Opelka, MD, FACS. Colon and Rectal Surgeon, Medical Director, Quality and Health Policy, Division of Advocacy and Health Policy, American College of Surgeons. New APMs in Development for QPP. Eighth National Alternative Payment Model (APM) and Accountable Care Organization (ACO) Summit. June 28, 2017. Washington, DC.

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[xli] **Limited-scale testing** of the proposed payment model is used when the PTAC determines a proposal meets all or most of the Secretary's criteria but lacks sufficient data to (1) estimate potential costs, savings, or other impacts of the payment model and/or (2) specify key parameters in the payment model and the PTAC believes the only effective way to obtain those data would be through implementation of the payment model in a limited number of settings; **Implementation of the proposed payment model**; or **Implementation of the proposed payment model as a high priority** will be those that are rated as "meets the criterion and deserves priority consideration" on multiple criteria, particularly the criteria designated by the PTAC as "high priority" criteria.

[xlii] Supra note 4. Sec 1115A of the Affordable Care Act stipulates that in order to expand a CMMI model, (1) the Secretary must determines that such expansion is expected to (A) reduce spending under applicable title without reducing the quality of care; or (B) improve the quality of patient care without increasing spending; (2) the Chief Actuary of the Centers for Medicare & Medicaid Services must certify that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and (3) the Secretary must determine that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals.

[xliii] CMMI Model Certification. Available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/CMMI-Model-Certifications.html

[xliv] Federal Advisory Committee Act (FACA), enacted in 1972, is a federal law governing the establishment and operation of advisory committees. The law is intended to ensure that advice by the various advisory committees is objective and accessible to the public.

[xlv] Future Directions for APM Development: The Role of P-TAC. Eighth National Alternative Payment Model (APM) and Accountable Care Organization (ACO) Summit. June 29, 2017. Washington, DC.

[xlvi] Nichols, Len. Future Directions for APM Development: The Role of P-TAC. Eighth National Alternative Payment Model (APM) and Accountable Care Organization (ACO) Summit. June 29, 2017. Washington, DC.

[xlvii] Statement of Jeffrey Bailet and Elizabeth Mitchell. Medicare Access and CHIP Reauthorization Act of 2015: Examining Physician Efforts to Prepare for Medicare Payment Reforms. Subcommittee on Health of the Committee on Energy and Commerce, U.S. House of Representatives. November 8, 2017. Available at http://docs.house.gov/meetings/IF/IF14/20171108/106599/HHRG-115-IF14-Wstate-MitchellE-20171108.pdf

[xlviii] Bipartisan Budget Act of 2019. Pub.L. 115–123. Sec. 51003 (b). Physician-focused Payment Model Technical Advisory Committee Provision of Initial Proposal Feedback.

[xlix] Miller, Harold. Accelerating Payment Reform in Medicare: How CMS Can Implement More Successful

[l] Health Care Innovation Awards. National Council of Young Men's Christian Associations of the United States of America (YMCA of the USA): Delivery on the promise of diabetes prevention program. Available at https://innovation.cms.gov/initiatives/participant/Health-Care-Innovation-Awards/YMCA-Of-The-USA.html

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[lvi] Miller, Harold. Accelerating Payment Reform in Medicare: How CMS Can Implement More Successful Alternative Payment Models More Quickly. Center for Healthcare Quality & Payment Reform. November 2017. Available at http://www.chqpr.org/downloads/AcceleratingPaymentReforminMedicare.pdf

[lvii] Stankiewicz, Mike. Medicare's New Payment Model May Sow Confusion. Bloomberg BNA. January 24, 2018.

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Appendix

Model case study: Project Sonar

On December 21, 2016, the Illinois Gastroenterology Group (IGG) and SonarMD submitted their "Project Sonar" model to PTAC as a "specialty-based intensive medical home" to "improve the management of patients with chronic disease."[lix] First deployed in 2013 by IGG for patients with Crohn's Disease, the model uses clinical decision support tools to assist teams of providers in identifying optimal care for patients, including appropriate use of medications, and a team of nurse care managers to identify and manage risky patients. Patients are engaged on at least a monthly basis via a "ping" to self-report symptoms, which are then used to score patients and identify which ones may require more focused attention from the nurse care managers or physicians. Practices receive per member per month (PMPM) payments to cover infrastructure for participating. Additionally, the APM entity may be eligible for shared savings up to 10% or be required to repay losses up to 5% based on retrospective reconciliation against a financial target price.

The PRT released its initial assessment of the model on March 22, 2017, recommending to the full PTAC that the model not be recommended to HHS for implementation.[lx] Of the ten criteria, the PRT unanimously determined that the model only satisfied three (flexibility, ability to be evaluated, and patient safety), none of which are "high priority" criterion. Among other concerns, the PRT decided that the proposal failed to demonstrate how the model could be applied to conditions beyond Crohn's Disease or be scaled; lacked "comprehensive and robust quality measures," and was not convincing that "a new payment model [was] necessary to achieve the goals" of the model.

After deliberation by the full committee on April 10th, the PTAC recommended to HHS that the model be tested "on a small scale with Medicare beneficiaries…to better discern whether the proposal can fulfill its promise in the Medicare population," while stating that "some concerns could likely be resolved through technical assistance."[lxi] The committee concluded that the model met all but two criteria (payment methodology and integration and care coordination) With respect to payment, the committee was concerned about whether the model is "structured appropriately to hold providers accountable for total cost of care," particularly given that Medicare patients are more likely to have multiple chronic conditions beyond Crohn's Disease that would affect care; whether providers could "cherrypick" to avoid complex patients; and whether new payment beyond a chronic care management fee would result in significant behavior change and clinical improvement. With respect to care coordination, the PTAC expressed concerns that the proposal did not fully address coordination with other providers, or consider how effective the existing technology would work with a Medicare population less inclined to engage with and use technology. Despite these concerns, PTAC supported the proposal's care model and goals and believed that the model had "promise" worthy of further testing to address any deficiencies before wider deployment.

On September 7, 2017, HHS Secretary Tom Price responded to PTAC's comments and recommendations on Project Sonar, indicating HHS would not pursue testing of the model, but "request[ing] that CMS reach out to the [submitters] to involve them in HHS' development of specialty models."[lxii] HHS agreed with the PTAC that the proposal was deficient in its payment methodology and care coordination, while also emphasizing concerns that the model is "too dependent on a proprietary software platform" that may not be available to other provider organizations or come at a cost in broader model application; the limited population of Medicare beneficiaries with inflammatory bowel disease; and the lack of outcomes-based quality measures.

There are a few key takeaways from the experience and process related to review of Project Sonar. First, the time between proposal submission and final determination by HHS was more than 8 months, reflecting the significant length of time needed to complete a full review cycle. This time does not even include the significant work that must be done before submission, including strategic planning, conducting necessary background research; identifying and convening potential partners; and crafting a concise proposal with sufficient evidence, data, and appendices to support the model concept. Furthermore, submitters must remain engaged through the review process and be prepared to dedicate time for ongoing communication with the PTAC for follow-up questions and clarification.

Second, approval at one level of review is not an assurance that the model is likely to be implemented. As indicated elsewhere in this paper, Project Sonar is one of multiple models that were not recommended by the PRT for implementation, but were recommended for full or partial implementation by the full PTAC. As noted, HHS ultimately decided not to proceed with the model, echoing many of the concerns that were first raised by the PRT In other words, the level of scrutiny of a given model may we impacted by the length and level of deliberation, and by competing conceptions of what makes for a good model.

Third, HHS will likely continue to set a high bar for what it thinks is an acceptable model for implementation (full or limited) within federal healthcare programs. HHS has strong incentives to only implement models that it believes will be financially beneficial to the federal government, fill an existing payment model gap or need, and result in measurable improvements in beneficiary health. The motivations and criteria driving HHS decision making, while similar to those required by PTAC, are going to first and foremost focus on long-term sustainability and impact for its programs.

Collectively, these takeaways demonstrate the significant challenges for submitters to win a recommendation for implementation of a model by CMS. While HHS has shown a willingness to work with submitters to improve their models or identify new opportunities, such as was the case with Project Sonar, HHS is likely to continue upholding strict standards for consideration.

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